

# Introduction

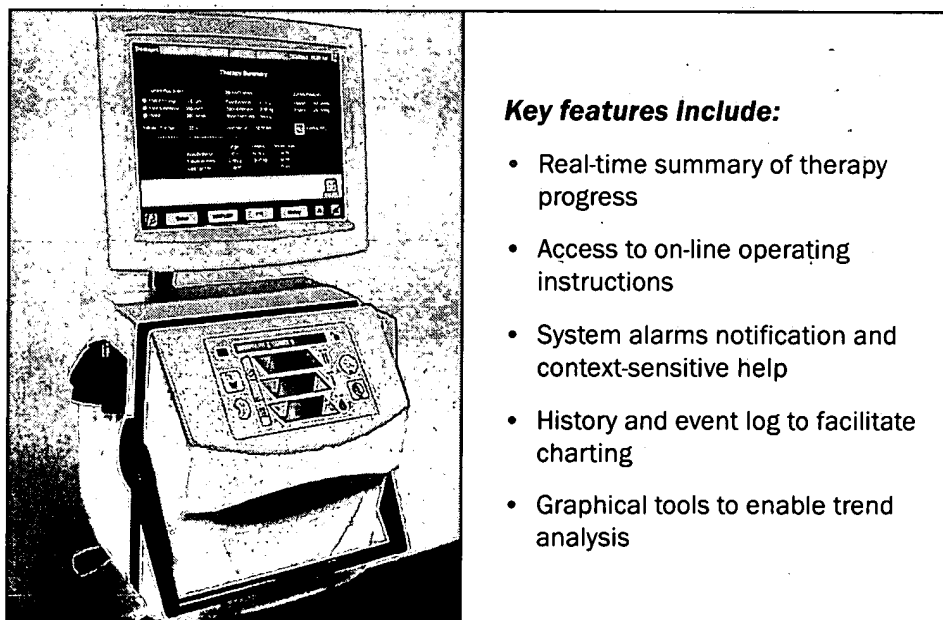
*Congratulations on choosing the OneView Operator Interface Accessory for the NxStage System One. This section will introduce you to some of OneView's key features and requirements before you get started.*

- *Warnings and precautions*
- *Disclaimer*
- *Product return procedure*

OneView is an optional graphical, touch-screen interface used with the NxStage System One to assist in therapy monitoring and charting and to provide on-line, context-sensitive help.

OneView only RECEIVES data from the NxStage Cyclor. OneView cannot control the cyclor. OneView displays information about the cyclor's current operation and logs/charts this data, including: current alarms, warnings/precautions, pump rates/volumes, pressures, and other cyclor parameters. Additional information displayed on OneView from the NxStage System One includes labeling that assists the user in setup, operation, and troubleshooting the cyclor's alarms.

*Figure 1. NxStage System One with OneView*



## **Key features include:**

- Real-time summary of therapy progress
- Access to on-line operating instructions
- System alarms notification and context-sensitive help
- History and event log to facilitate charting
- Graphical tools to enable trend analysis

## **Introduction**

---

This instruction for use is a supplement to the NxStage System One Operator's Manual and provides specific instructions for the optional OneView Operator Interface Accessory. This instruction for use should be used in conjunction with the NxStage System One Operator's Manual.



## Warnings

1. Data displayed by OneView does not substitute for that displayed on the NxStage Cycler control panel. The control panel shall be considered correct. In the unlikely event that other information displayed by OneView differs from that of the cycler control panel or the NxStage System One Operator's Manual, the cycler control panel shall be considered correct.
2. Do not connect additional multiple portable socket-outlets or extension cords to the isolation device.
3. Do not connect any items to OneView which are not specified as part of the system.



## Precautions

1. Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner.)
2. Procedures using the NxStage System One with OneView must be performed under physician prescription.
3. It is the health care provider's responsibility to ensure that product return procedures are followed. Before returning OneView to NxStage, it must be prepared and packaged per the NxStage Medical, Inc. return policy (see the "Product Return Procedure" in this manual).
4. Do not use OneView with any system other than NxStage System One. Performance has not been validated with any other device.
5. There are no operator or customer technician serviceable parts in or on OneView. NxStage Medical, Inc. or its agent must perform maintenance and/or repair.
6. Ensure that all OneView components (e.g. touch-screen, UPS, etc.) labeling and instructions for use are available at the treatment site as a reference to the operator.
7. The OneView Operator Interface may only be used by trained and fully qualified persons in the operation of both the NxStage System One and OneView.
8. The isolation device (UPS or isolation transformer) provided by NxStage Medical is medical-grade equipment and must be used with OneView. Do not use an isolation device other than the one provided with OneView as other isolation devices have not been validated for use with OneView.
9. The OneView touch-screen and computer are non-medical grade equipment. These components must be connected to the isolation device provided by NxStage Medical to meet the Electric Shock and Leakage Current requirements for medical-grade equipment. The power cords for the OneView touch-screen and computer shall not be removed from the isolation device and plugged directly into a wall outlet.
10. OneView shall not be used with non-medical grade equipment which has not been provided with the system. OneView has not been validated for use with non-medical grade equipment.
11. Initial installation of OneView must be performed by NxStage Medical, Inc. or its agent.
12. To avoid damaging the OneView computer, power off the computer prior to turning off the isolation device or unplugging the isolation device from the wall outlet.
13. If the power or communication to OneView is interrupted or the OneView program is terminated during treatment, a power fail recovery procedure must be performed, otherwise some displayed data may be inaccurate (see Section Three: Maintenance and Troubleshooting).

### Disclaimer

NxStage Medical is not responsible or liable for any failure of performance of the NxStage System One with OneView where such failure is due, in whole or in part, to any misuse or modification of the System or its operation, including, without limitation:

- Failure to have all operating procedures performed by a fully trained and qualified person;
- Failure to maintain a proper electrical hookup in full compliance with all applicable codes, OneView's specifications and if applicable, IEC requirements;
- Failure to operate OneView at all times in accordance with the operator's manual.

### Product Return Procedure

To return product to the company, a return authorization (RA) number is required.

If patient treatments have been performed with the NxStage System One, OneView must be cleaned in accordance with the cleaning instructions in *Section Three: Maintenance* of the Operator's Manual prior to packing and shipping.

Contact NxStage Medical Customer Service to obtain an RA number and instructions for packing, labeling and shipping.



---

**PRECAUTION**

**It is the health care provider's responsibility to ensure that product return procedures are followed. Before returning OneView to NxStage, it must be prepared and packaged per the NxStage Medical, Inc. return policy. (See the "Product Return Procedure" in this manual).**

---

Contact:

NxStage Medical, Inc.  
Attn: Customer Service  
439 South Union Street, 5th Floor  
Lawrence, MA 01843-2800  
**Phone: 866-697-8243**  
**Fax: 978-687-4809**  
**E-mail: customerservice@nxstage.com**

# Section One: OneView Connections

*This section provides a description of the electrical connections and power on/off sequences.*



---

## **WARNINGS**

- Data displayed by OneView does not substitute for that displayed on the NxStage Cycler control panel. The control panel shall be considered correct. In the unlikely event that other information displayed by OneView differs from that of the NxStage System One Operator's Manual, the Operator's Manual shall be considered correct.
- Do not connect additional multiple portable socket-outlets or extension cords to the Isolation device.
- Do not connect any items to OneView which are not specified as part of the system.

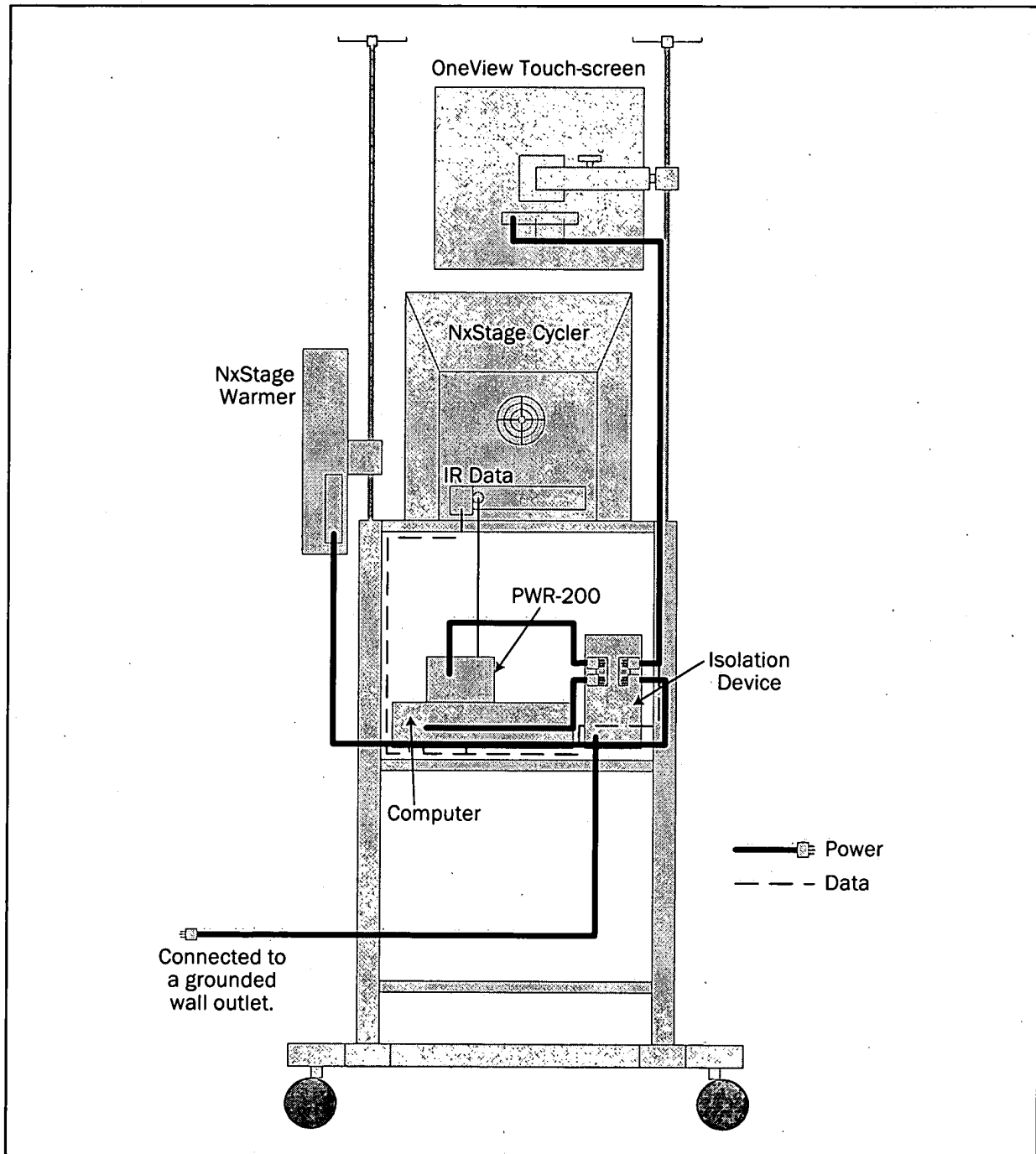
## **PRECAUTIONS**

- The OneView Operator Interface may only be used by operators properly trained in the operation of both the NxStage System One and OneView.
  - The Isolation device (UPS or Isolation transformer) provided by NxStage Medical is medical-grade equipment and must be used with OneView. Do not use an Isolation device other than the one provided with OneView as other Isolation devices have not been validated for use with OneView.
  - The OneView touch-screen and computer are non-medical grade equipment. These components must be connected to the Isolation device provided by NxStage Medical to meet the Electric Shock and Leakage Current requirements for medical-grade equipment. The power cords for the OneView touch-screen and computer shall not be removed from the Isolation device and plugged directly into a wall outlet.
  - OneView shall not be used with non-medical grade equipment which has not been provided with the system. OneView has not been validated for use with non-medical grade equipment.
  - Initial Installation of OneView must be performed by NxStage Medical, Inc. or its agent.
-

## OneView Connections

Prior to operating OneView, verify the connections of each of the components as illustrated in Figure 2.

*Figure 2. OneView Setup (rear view)*



**OneView Power On Sequence**

In order for OneView to recognize the connections to the NxStage System One, each component must be powered on in the following order:

1. Plug in the isolation device (see Figure 2) and power on.
2. Power on the computer and touch-screen.

Note: In most cases, the computer and touch-screen should power on automatically.

Allow the computer to fully power on prior to the cyclor so that all appropriate data can be collected by OneView.

3. Power on the NxStage Cyclor.
4. Power on the NxStage Warmer (if applicable).



---

**PRECAUTION**

**To avoid damaging the OneView computer, power off the computer prior to turning off the Isolation device or unplugging the Isolation device from the wall outlet.**

---

**OneView Power Off Sequence**

1. Power off the NxStage Warmer (if applicable).
2. Power off the NxStage Cyclor.
3. Power off the computer and wait for the “blank” touch-screen.
4. Unplug the isolation device.

**Notes:**



# Section Two: OneView Operations

*This section outlines use of OneView during patient treatments with the NxStage System One.*

- Overview
- Standby
- Therapy summary (Normal; Caution or Alarm Conditions)
- SIMPLER
- FYI
- History
- Graphical analysis tool
- Setup



---

## **WARNING**

Data displayed by OneView does not substitute for that displayed on the NxStage Cyclor control panel. The control panel shall be considered correct. In the unlikely event that other information displayed by OneView differs from that of the NxStage System One Operator's Manual, the Operator's Manual shall be considered correct.

## **PRECAUTIONS**

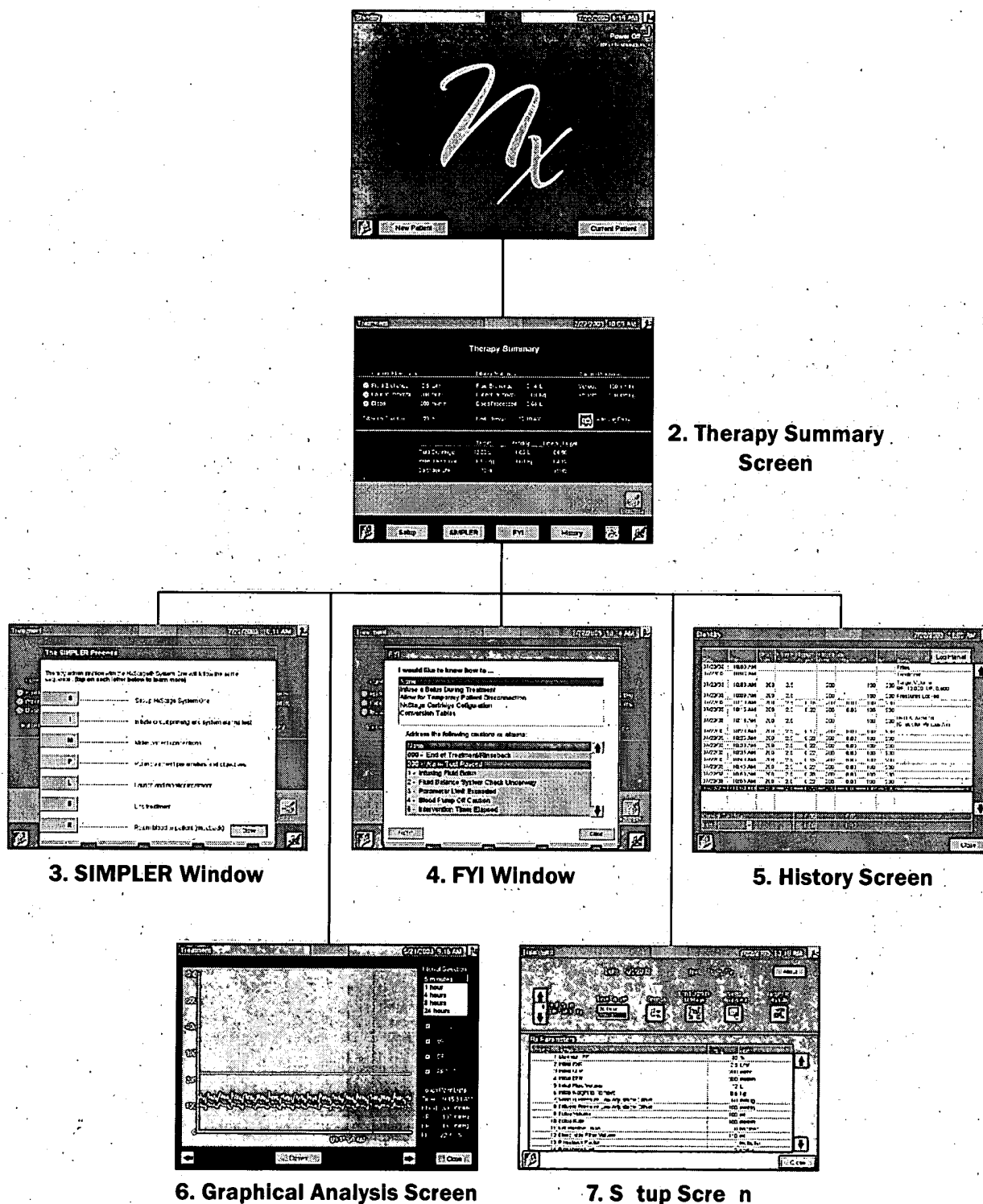
- The OneView Operator Interface may only be used by operators properly trained in the operation of both the NxStage System One and OneView.
  - If the power or communication to OneView is interrupted or the OneView program is terminated during treatment, a power fall recovery procedure must be performed, otherwise some displayed data may be inaccurate (see Section Three: Maintenance and Troubleshooting).
- 

OneView is a touch-screen driven, graphical operator interface to aid a trained operator in treatment operations, troubleshooting, and charting. Its hierarchical and context-sensitive structure simplifies the interface, while allowing easy, one-touch access to important information.

The following pages describe the overall organization of the system and the features and information accessed from each screen.

10

## 2. Therapy Summary Screen

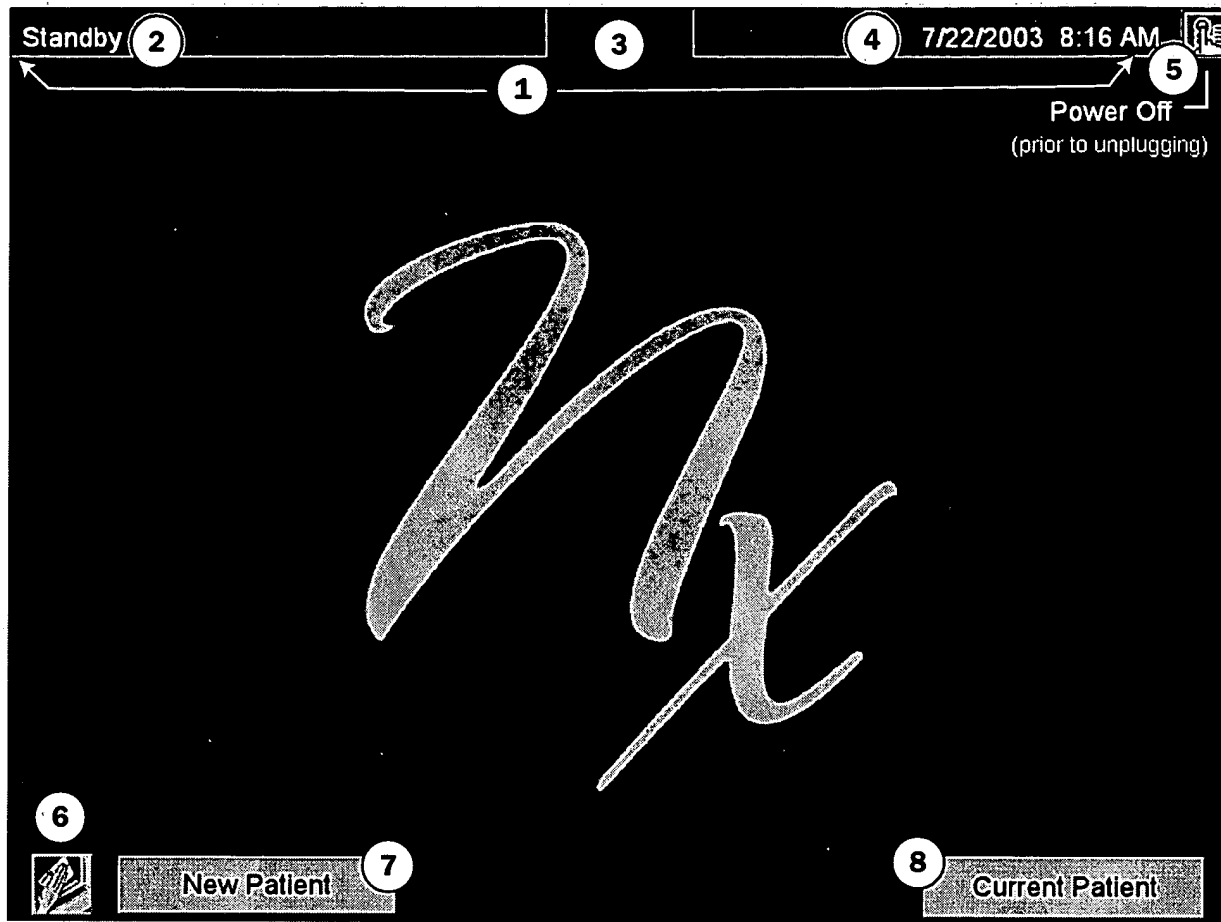


## **Overview**

OneView has seven primary screens/windows as described below. In depth information on each individual screen/window is detailed throughout this section.

- 1. Standby** – Appears when OneView is turned on, and allows the operator to choose whether a new treatment is initiated or a previous treatment is continued.
- 2. Therapy Summary** – Serves as the “home screen” for the treatment. Basic summary parameters (flow rates, treatment volumes administered during the interval, and pressures) are displayed, as is the operational/alarm status of the NxStage System One. When the NxStage system is in an caution or alarm condition, context-sensitive troubleshooting help is accessible. All other screens are accessed from this screen.
- 3. SIMPLER** – Allows the operator to access the on-line version of the Summary Operations Guide for the NxStage System One. SIMPLER is the acronym for the sequence of steps to administer therapy with the NxStage System One.
- 4. FYI** – Provides additional information about other system features that an operator may intermittently access during patient treatment, e.g., infusion of a bolus of fluid or blood recirculation.
- 5. History** – Captures and summarizes patient therapy information over time, both at prespecified intervals and for key events such as alarm conditions and operator interventions.
- 6. Graphical Analysis Tool** – Graphically represents blood flow, venous pressure, effluent pressure, and filtration fraction over time to allow advanced trend analysis and troubleshooting.
- 7. Setup** – Allows the advanced operator to customize parameters.

Figure 4. Standby Screen



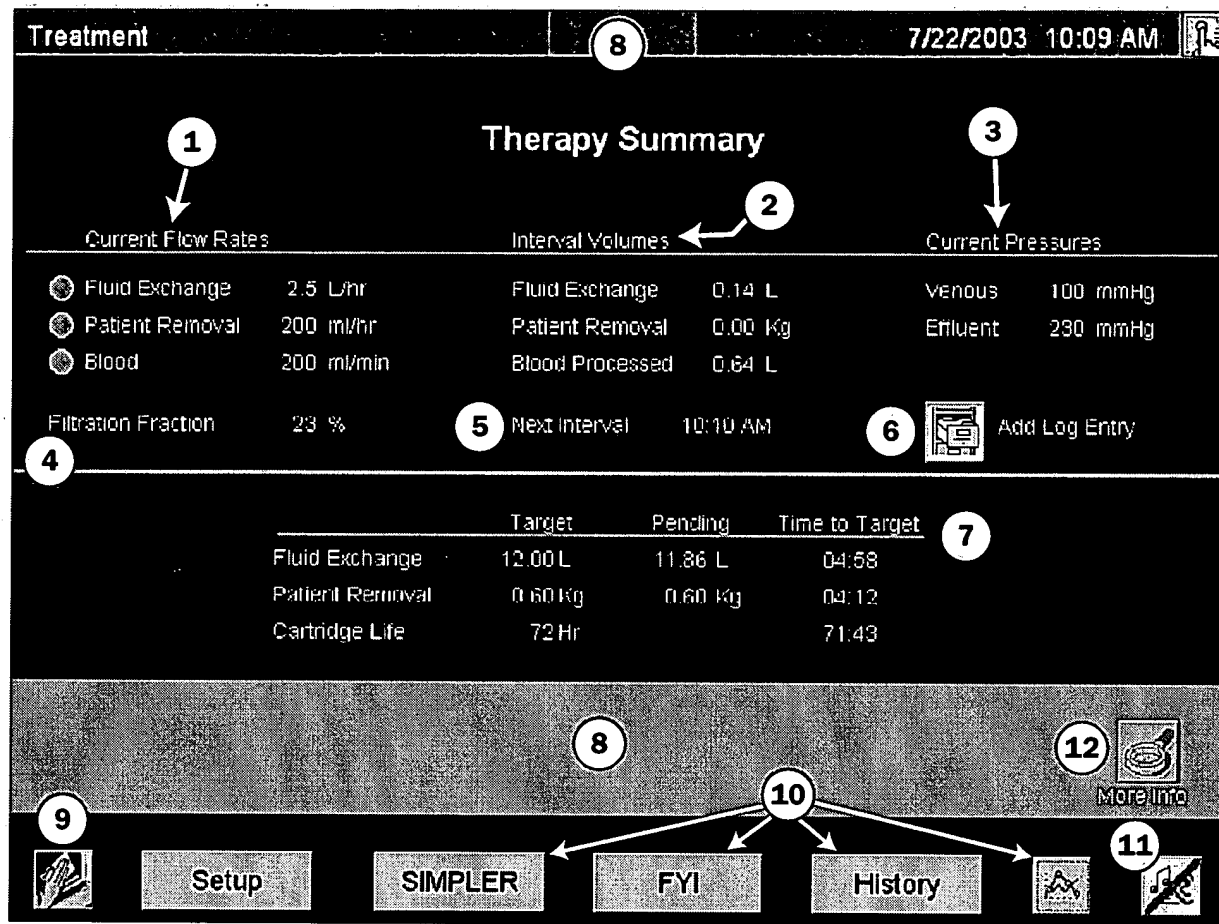
**Standby** (see Figure 4)

The primary function of the “Standby” screen is to allow the operator to either initiate a new patient treatment (clearing the stored patient history) or to append history from the prior treatment

- 1. Title Bar** – The title bar appears at the top of every screen and displays the system mode, color status, and date/time.
- 2. System Mode** – The current operational mode of the NxStage System One (e.g., stand-by, prime, therapy, and rinse-back).
- 3. Color Status** – Uses color to indicate whether the NxStage System One is currently in Green Operating Condition, Yellow Caution Condition, or Red Alarm Condition.
- 4. Date/Time** – Displays date and time.
- 5. Power Off** – Allows the operator to power off the computer. The operator must press and hold for one second.
- 6. Clean Screen** – Disables the touch screen for 10 seconds so that the operator may wipe down the display.
- 7. New Patient** – Allows the operator to choose to begin a new patient treatment. If an operator chooses this option, he/she will be asked to confirm this choice. Previous treatment information will no longer be accessible.
- 8. Current Patient** – Allows the operator to append history from the prior treatment. All NxStage System One treatment data subsequently generated will be added to the database of the prior treatment.

Note: OneView will return to the Standby Screen when inactive.

Figure 5. Therapy Summary Screen – Normal Condition



**Therapy Summary – Normal Condition** (see Figure 5)

This serves as the “home screen” during treatment operations. Basic summary parameters (flow rates, treatment volumes administered during the interval, and pressures) are displayed, as is the operational/alarm status of the NxStage System One. In addition, all other screens are accessible from this screen.

- 1. Current Flow Rates and “Pump On” Indicators** – Displays the current prescription fluid, net patient fluid removal, and blood flow rates commanded by the NxStage System One. For example, in the Figure 5, all pumps are “on.”
- 2. Interval Volumes** – Displays the accumulated volumes of prescription fluid, net patient fluid removal, and blood processed during the current treatment interval (interval lengths are operator-defined using the Log Interval Selector – see “Setup”). In addition, the time that has passed during the current interval is displayed.
- 3. Current Pressures** – Displays the current venous and effluent pressures.
- 4. Filtration Fraction** – The percentage of blood flow that passes through the filter as plasma water.
- 5. Next Interval** – Time of next log interval reading.
- 6. Add Log Entry** – Inserts a snapshot of current therapy parameters into the therapy history. This snapshot can then be accessed in the “History” screen.
- 7. Time to Target** – This provides an estimate of time required to reach the target RxF and patient removal volumes, and an estimate of the remaining cartridge lifetime.
- 8. Operational Status** – Uses color to indicate whether the NxStage System One is currently in Green Operating Condition, Yellow Caution Condition, or Red Alarm Condition. In addition, displays the numerical alarm and description of which Caution or Alarm Condition is currently active.
- 9. Clean Screen** – Disables the touch screen for 10 seconds so that the operator may wipe down the display.
- 10. Access to Additional Screens** – Bottom buttons allow operator to access SIMPLER, FYI, History, and Graphics tools.
- 11. Mute** – Silences OneView audible alarms (but not NxStage System One audible alarms).
- 12. More Info** – Access to probable causes and corrective measures for active cautions or alarms.

## Section 2: OneView Operations

Figure 6. Therapy Summary Screen – Caution or Alarm Condition

Treatment
7/22/2003 10:13 AM

1

### Therapy Summary

Current Flow Rates		Interval Volumes		Current Pressures	
Fluid Exchange	0.5 L/hr	Fluid Exchange	0.13 L	Venous	100 mmHg
Patient Removal	ml/hr	Patient Removal	0.00 kg	Effluent	250 mmHg
Blood	0 ml/min	Blood Processed	0.71 L		
Filteration Fraction	25 %	Next Interval	10:20 AM	Add Log Entry	

	Target	Remaining	Time to Target
Fluid Exchange	12.00 L	11.47 L	04:17
Patient Removal	0.60 kg	0.60 kg	04:03
Cartridge Life	72 Hr		71:24

1
**RED ALARM 10 - Check for Venous Air**

Setup
 SIMPLER
 FYI
 History

Treatment
7/22/2003 10:18 AM

2

### Therapy Summary

Current Flow Rates		Interval Volumes		Current Pressures	
Fluid Exchange	0.5 L/hr	Fluid Exchange	0.13 L	Venous	100 mmHg
Patient Removal	ml/hr	Patient Removal	0.00 kg	Effluent	250 mmHg
Blood	0 ml/min	Blood Processed	0.71 L		
Filteration Fraction	25 %	Next Interval	10:20 AM	Add Log Entry	

	Target	Remaining	Time to Target
Fluid Exchange	12.00 L	11.47 L	04:17
Patient Removal	0.60 kg	0.60 kg	04:03
Cartridge Life	72 Hr		71:24

2
**RED ALARM 10**

**Probable Cause:**  
1. Air entering blood circuit  
2. Arterial connection loose (patient to blood pump)  
3. Arterial access dislodged or disconnected  
4. Air in fluid

**Corrective Measure:**  
Perform Venous Air Recover:  
a. Press MUTE  
b. Clamp between filter and venous injection site  
c. Attach syringe to venous injection site  
d. Press STOP  
e. Extract air  
f. Inject blood back  
g. Remove syringe, unclamp between filter and injection site

Close

Setup
 SIMPLER
 FYI
 History



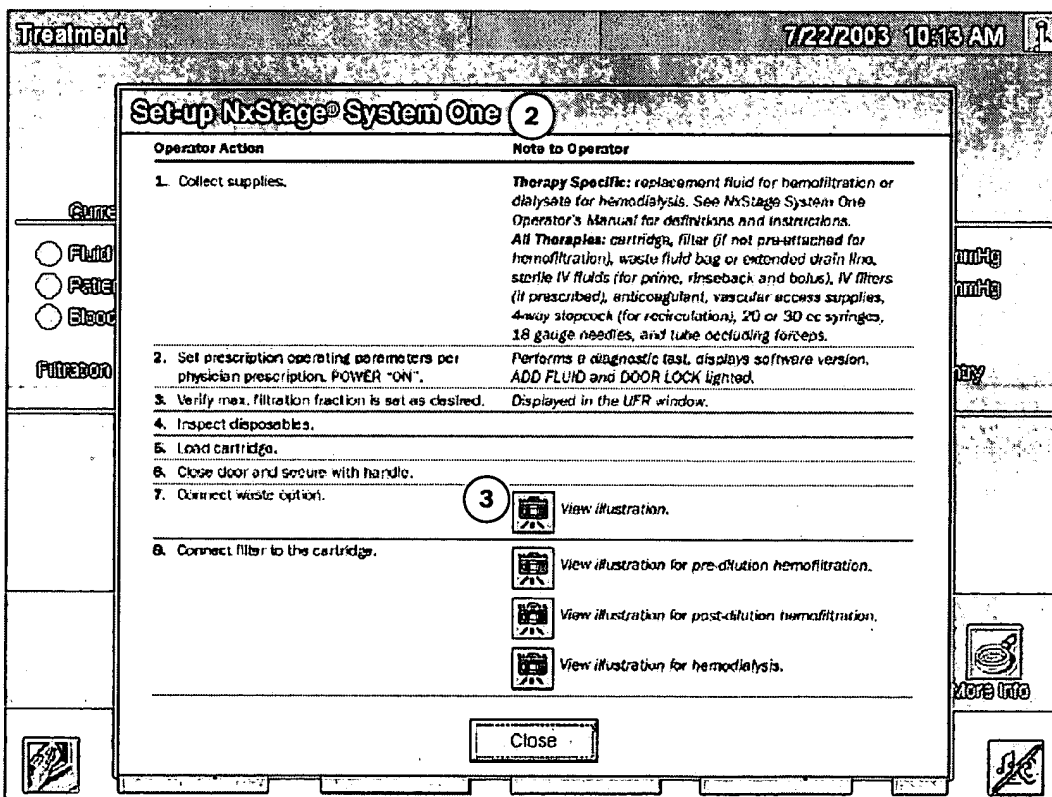
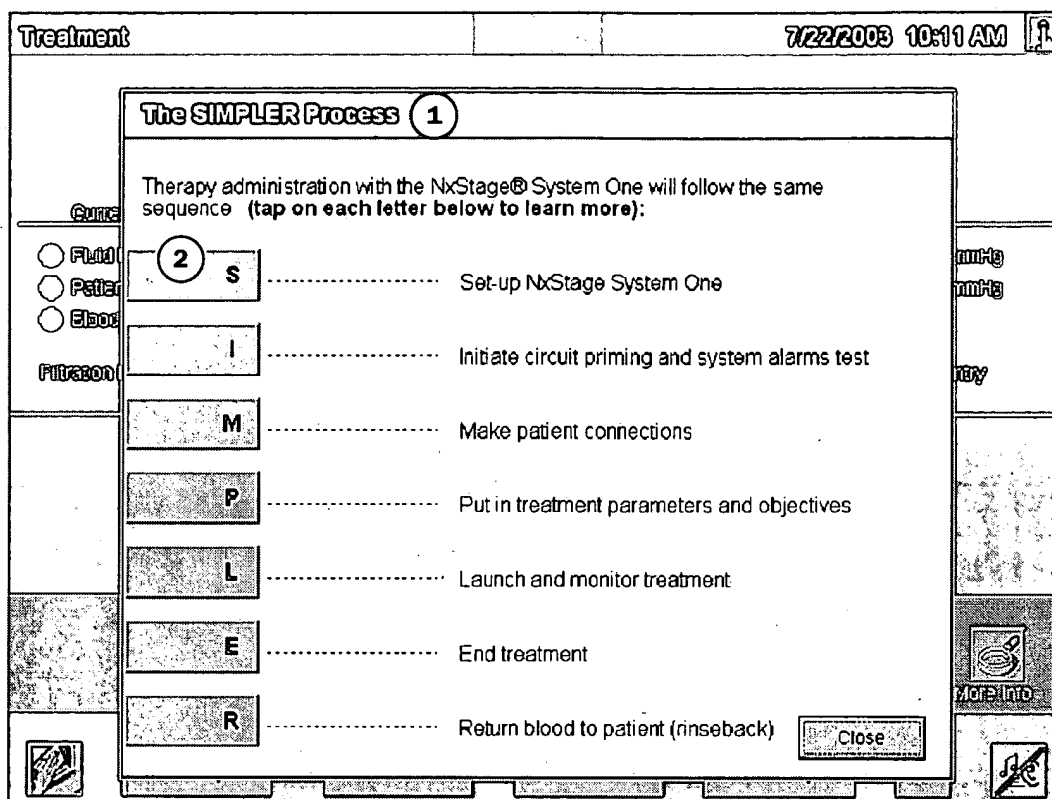
### **Therapy Summary – Caution or Alarm Condition** (see Figure 6)

When the NxStage System One enters a Caution or Alarm Condition, OneView responds to indicate the change in operational status.

- 1. Therapy Summary Screen** (when Caution or Alarm condition is present) – If the NxStage System One enters a Caution or Alarm Condition, the Operations Status areas will change to yellow or red, respectively. In addition, a text indicator of Caution or Alarm Condition will appear inside the lower Operational Status window. The operator may access additional information by pressing the “More Info” button.
- 2. Additional Condition Information** (accessed by pressing the “More Info” button) – An expanded description of the potential causes and potential resolutions of the Caution or Alarm Condition is displayed to assist troubleshooting. This information is taken from Section Four: Alarms and Safety Systems of the NxStage System One Operator’s Manual. The operator may return to the “Therapy Summary” screen by pressing the “Close” button.

The Caution or Alarm Condition notification will remain on the OneView display until the condition is resolved on the NxStage System One.

Figure 7. SIMPLER Screen



**Simpler** (see Figure 7)

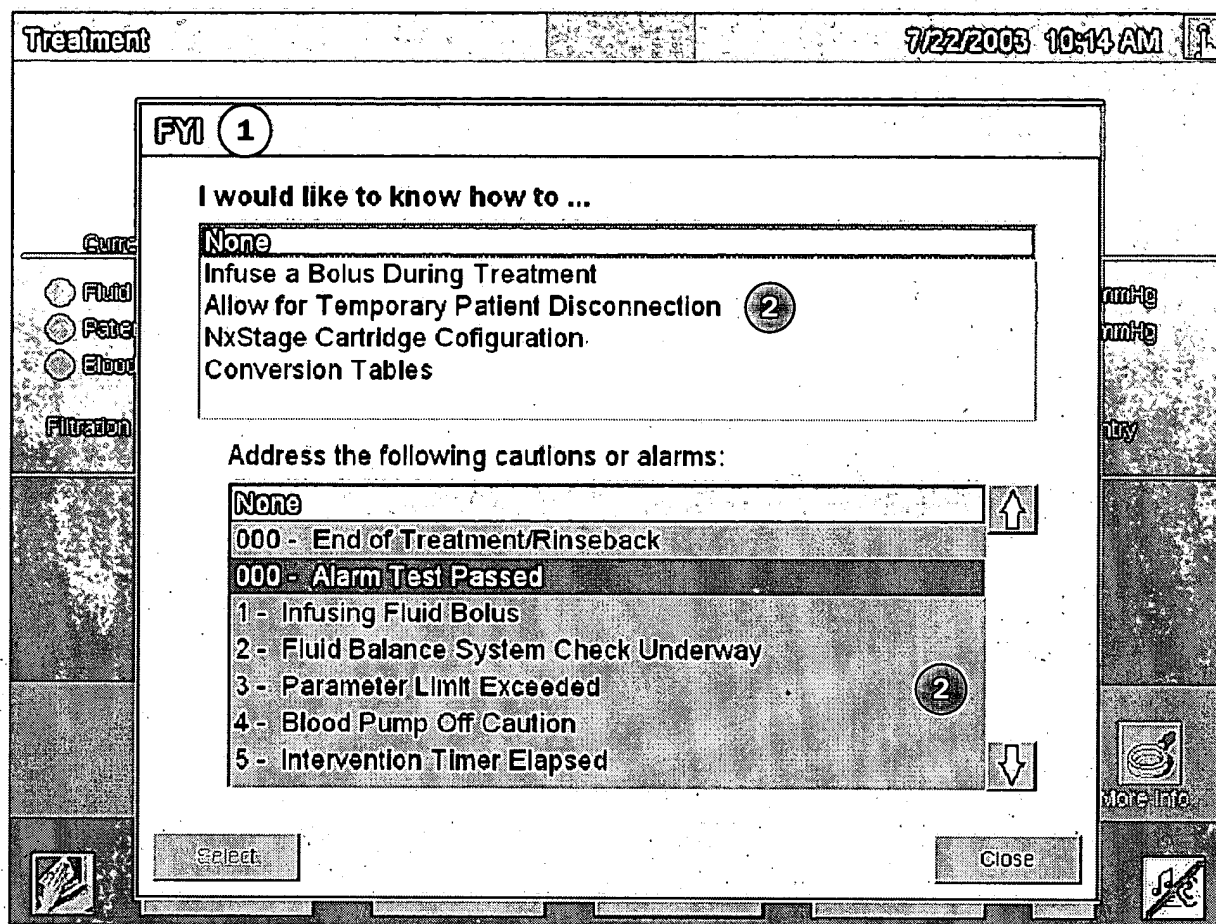
The operator can access an on-line summary of the NxStage System One operating instructions by pressing the SIMPLER button on the Therapy Summary Screen.

- 1. SIMPLER Process Menu** – Outlines the major steps to operate the NxStage System One. Additional step detail can be accessed by pressing the grey letter box to the left of the respective step of interest.
- 2. Detailed Step Instructions** – Step detail (an on-line version of the NxStage System One Operation Summary and Alarm Chart) is displayed for the respective step of interest.
- 3. Step Illustrations** – Graphical instructions for certain steps (e.g., required connections, displays) can be accessed when the “Illustration” key is pressed.

This information may be accessed at any time during the treatment.

The operator may return to the “Therapy Summary” screen by pressing the “Close” button.

Figure 8. FYI Screen



### **FYI** (see Figure 8)

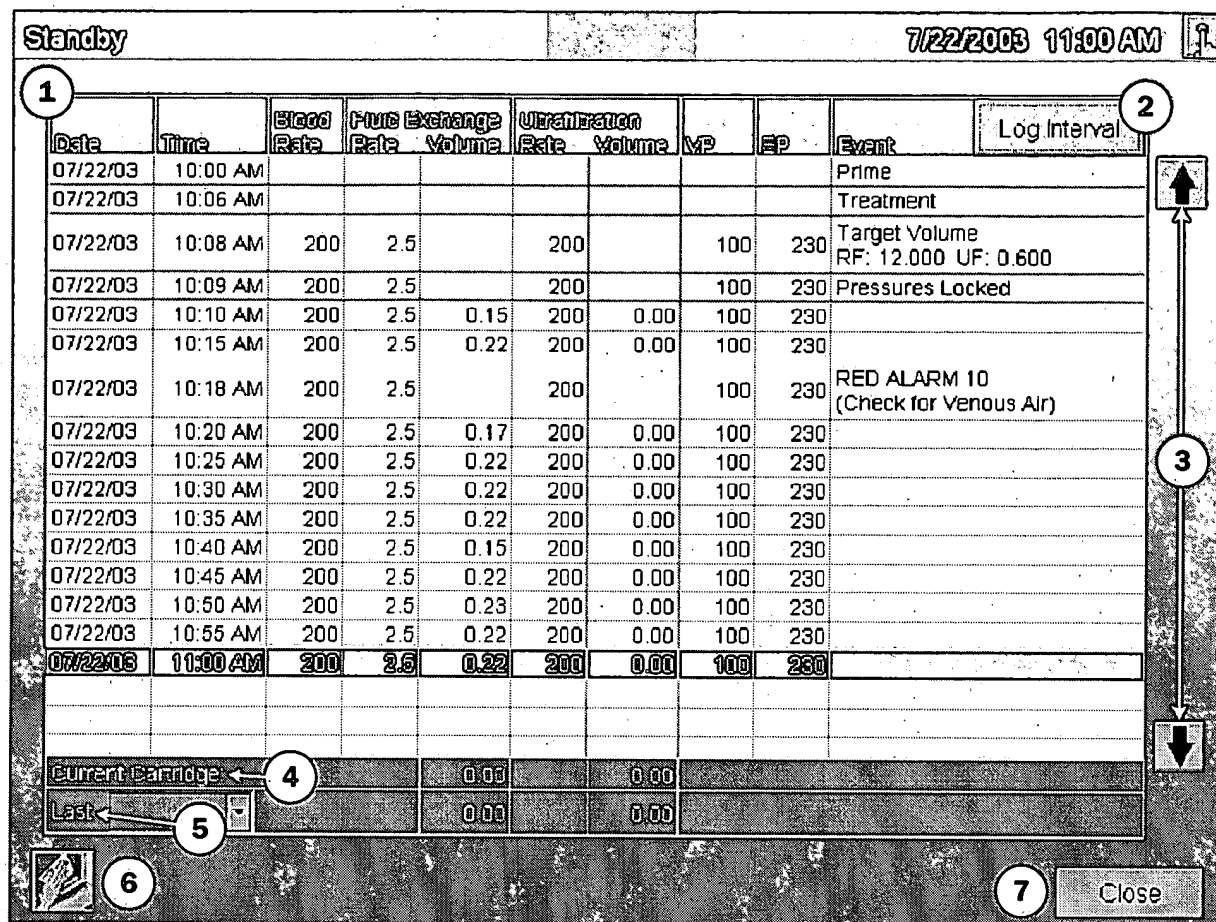
The “FYI” screen provides additional information about other system features that an operator may access during patient treatment.

- 1. Main FYI Screen** – Provides the menu of items for which additional information is available. To select one of these items, the Operator must highlight the item of interest using the touch screen and then press “Select.”
- 2. Additional Information** – Step detail (an on-line version of the NxStage System One Operation Summary and Alarm Chart) is displayed for the respective step of interest.

The operator may return to the “Therapy Summary” screen by pressing the “Close” button.

## Section 2: OneView Operations

**Figure 9. History Screen**



**History** (see Figure 9)

The “History” screen captures and summarizes patient therapy information over time, both at prespecified intervals and for key events such as alarm conditions and operator interventions. Information can be summarized in multiple ways, depending on operator preferences.

1. **Data History Table** – In tabular format, summarizes therapy parameter information over time.
2. **Show All/Log Interval** – When “Show All” is selected (as in Figure 9), both regular interval (as defined in “Setup”) therapy data and all additional data records (e.g., operator interventions, alarms, operator log entries) are displayed in the table. When “Log Interval” is selected, only regular interval therapy data will be displayed.

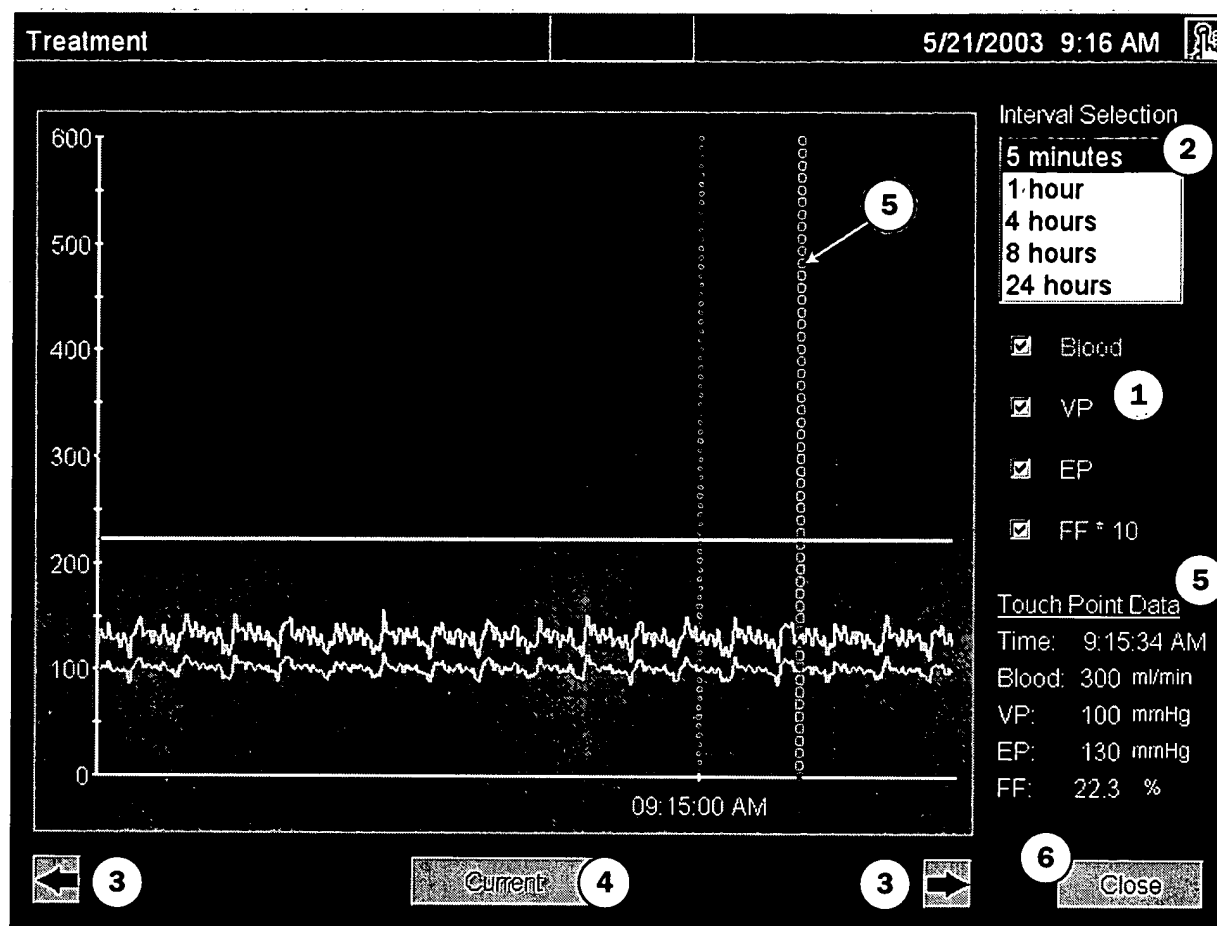
Note: If a power or communication recovery on OneView is performed during treatment, then an entry will exist in the history log stating when communication was lost and when it was restored. Additionally, the next log interval will state in the event column that it is only displaying the volume since communication was restored.

3. **Scroll Arrows** – Allows the operator to scroll throughout the current patient therapy
4. **Current Cartridge** – Summarizes both prescription fluid volume and net fluid removal for the current cartridge.
5. **Last (operator defined)** – Summarizes both prescription fluid volume and net fluid removal for the operator definable period. This can be defined as none, 4, 8, 12 or 24 hours. The definable period is selected using the drop down menu in the lower left corner. The beginning time can be chosen by selecting the desired row.

Note: If a power failure or system date/time change has occurred during an operator defined period, then the total volume for that period will not be displayed.

6. **Clean Screen** – Disables the touch screen for 10 seconds so that the operator may wipe down the display.
7. **Close** – Closes the “History” screen and returns operator to the “Therapy Summary” screen.

Figure 10. Graphical Analysis Screen





### **Graphical Analysis Tool** (see Figure 10)

This tool graphically charts blood flow (red), venous pressure (blue), effluent pressure (green), and filtration fraction (orange) over time to allow advanced trend analysis and troubleshooting. Information can be summarized in multiple ways, depending on operator preferences.

- 1. Data Display Choice** – Allows the operator to choose which data is displayed in the graph (items will be displayed when checked).
- 2. Interval Selection** – Allows selection of the time interval for data displayed on the screen from 5 minutes to 24 hours.
- 3. Scroll Arrows** – Allows the operator to scroll up and down the therapy data history table.
- 4. Current** – Pressing this button moves the graph to the current data position.
- 5. Touch Point Data** – The operator may display data readings for a specific point in time by touching a chosen point in time on the screen. A vertical dotted line will appear, and the appropriate time and data readings will appear in the data summary area in the lower right corner of the screen.
- 6. Close** – Closes the “Graph” screen and returns operator to the “Therapy Summary” screen.

Figure 11. Setup Screen

Treatment
7/22/2003 10:10 AM

1  
 Date: 7/22/2003

1  
 Time: 10:10 AM

1  
 About

2  
 History Log  
 Interval (min.)  
 5

3  
 Time Format  
 24 Hour  
 AM/PM

4  
 Sounds

5  
 Send Data to  
 NxStage

6  
 Video  
 Alignment

7  
 Return to  
 Standby

### Rx Parameters

Number	Name	Value	Units
1	Maximum FF	35	%
2	Initial FXR	2.5	L/hr
3	Initial UFR	200	ml/hr
4	Initial BFR	200	ml/min
5	Initial Fluid Volume	12	L
6	Initial Weight to Remove	0.6	Kg
7	Venous Pressure Low Adjustable Offset	60	mmHg
8	Effluent Pressure Low Adjustable Offset	100	mmHg
9	Bolus Volume	100	ml
10	Bolus Rate	100	ml/min
11	Net Positive Bolus	0	boolean
12	Blood-side Filter Volume	110	ml
13	Rinseback Factor	1	Multiplier
14	Rinseback Limit	2	scalar

9

10
 Close

**Setup** (see Figure 11)

The “Setup” screen allows the advanced operator to customize OneView parameters and to view the current parameter settings of the NxStage System One.

- 1. Date/Time** – Displays current system settings. Either may be reset by touching and holding the respective item display for 5 seconds and following the instructions that subsequently appear.
- 2. History Log Interval** – Allows the operator to choose the frequency at which OneView automatically logs therapy information into the history log. Choices are 5 minutes, 10 minutes, 15 minutes, 20 minutes, 30 minutes, and 60 minutes. Changing the log interval does not affect previously stored data.
- 3. Time Format** – 24 hour or AM/PM (12 hour).
- 4. Sounds** – Allows the operator to choose whether or not OneView will make a sound when the NxStage System One alarms. Different sounds and volumes can be chosen for Yellow Cautions not requiring intervention, Yellow Cautions requiring intervention, and Red Alarms, respectively. Note: this is an operator option – in the default setting OneView does not sound during alarms.
- 5. Send Data to NxStage** – Allows the operator to send current treatment service data to NxStage.
- 6. Video Alignment** – Utility to align touch sensing with display. This should be used in the event that the touch-screen is not responding as expected to operator’s actions (see Section Three: Maintenance and Troubleshooting).
- 7. Return to Standby Screen** – Pressing this button prior to start of patient treatment (Cycler System Mode = Treatment) allows the operator to begin a new patient therapy, erasing previously stored therapy information. If an operator chooses this option, he/she will be asked to confirm this choice.
- 8. Prescription Parameters** – Using the scroll arrows on the right side of the table, the operator can review the prescription parameter settings of the NxStage System One. More information on these settings can be found in the NxStage System One Operator’s Manual. The operator cannot change these settings from within OneView.
- 9. Clean Screen** – Disables the touch screen for 10 seconds so that the operator may wipe down the display.
- 10. Close** – Closes the “Setup” screen and returns operator to the “Therapy Summary” screen.

**Notes:**

# Section Three: Maintenance and Troubleshooting

*This section outlines minimal maintenance requirements of OneView.*

- *Inspection*
- *General cleaning*
- *Troubleshooting*



---

**There are no operator or customer technician serviceable parts in or on OneView. NxStage Medical, Inc. or its agent must perform maintenance and/or repair.**

---

## **Inspection**

Prior to each use, inspect the power supply cords for damage. Do not use OneView if damage is evident.

## **General Cleaning**

After every treatment (or as needed) clean and disinfect the surfaces of OneView's components and its stand:

1. Make sure OneView is OFF before performing a general cleaning.
2. Clean spills and smudges with a soft cloth and mild detergent solution (e.g., 1/2 ounce of mild detergent per 3 gallons water).
3. Disinfect external surfaces with isopropyl alcohol and a soft cloth.

### Troubleshooting

<b>Description</b>	<b>Probable Cause</b>	<b>Corrective Measure</b>
"Cycler software compatibility error"	Software version of OneView and cycler are not compatible.	Call NxStage Customer Service.
"Looking for cycler ..."	<ol style="list-style-type: none"> <li>1. Cycler NOT powered on.</li> <li>2. IR data receiver misaligned with IR window on cycler.</li> <li>3. Interference with another IR device.</li> </ol>	<ol style="list-style-type: none"> <li>1. Check connections and power on cycler.</li> <li>2. Realign IR data receiver as illustrated in Figure 2.</li> <li>3. Reposition system or shield IR data receiver.</li> </ol>
Standby screen displayed during treatment	<ol style="list-style-type: none"> <li>1. Cycler NOT powered on.</li> <li>2. IR data receiver misaligned with IR window on cycler.</li> <li>3. Interference with another IR device.</li> <li>4. Computer power failure.</li> </ol>	<ol style="list-style-type: none"> <li>1. Check connections and power on the cycler.</li> <li>2. Realign IR data receiver as illustrated in Figure 2.</li> <li>3. Reposition system or shield IR data receiver.</li> <li>4. Re-establish power and perform Power or Communication Failure Recovery procedure.</li> </ol>
Touch-screen is blank	<ol style="list-style-type: none"> <li>1. Touch-screen NOT powered on.</li> <li>2. Connections unplugged.</li> <li>3. Computer power failure.</li> </ol>	<ol style="list-style-type: none"> <li>1. Power on touch-screen or adjust contrast.</li> <li>2. Inspect connections, see Section 1.</li> <li>3. Re-establish power and perform Power or Communication Failure Recovery procedure.</li> </ol>
Touch-screen misalignment	Out of adjustment.	Locate the cursor by tapping lightly on the touch-screen until the cursor is located. Move the cursor to the video alignment button then tap to re-initiate video alignment procedure. If unsuccessful, contact NxStage Customer Service.



#### **PRECAUTION**

**If the power or communication to OneView is interrupted or the OneView program is terminated during treatment, a power fail recovery procedure must be performed, otherwise some displayed data may be inaccurate (see Section Three: Maintenance and Troubleshooting).**

## **Power or Communication Failure Recovery**

If power or communication is lost to OneView, data generated by the NxStage Cyclor during this time may not be accurately reflected in OneView. The following procedure will resynchronize data between the cyclor and OneView.

- 1.** Turn off Cyclor.
- 2.** Re-establish power to the computer and allow OneView to power-up completely.
- 3.** Turn on NxStage Cyclor and follow power failure recovery procedure for cyclor (see Section Five: Troubleshooting of the NxStage System One Operator's Manual).

**Note:** After a power failure or communication loss, the previous target volumes on the therapy summary screen will no longer be displayed.

**Notes:**



# Section Four: Specifications

*This section outlines specifications for OneView.*

- *Environmental requirements*
- *Electrical safety*
- *Electromagnetic compatibility*
- *Operation*

## Environmental Requirements

The operator's manual for each individual component shall be used to determine, at a minimum, the environmental operating and transport/storage conditions, in addition to all power and/or load requirements. Typical conditions are as follows:

<b>Parameter</b>	<b>Performance</b>
Ambient Operating Temperature	15° C to 37° C (59° F to 98° F)
Ambient Operating Humidity	0% to 90%, non-condensing
Maximum Operating Altitude	Not applicable
Transport/Storage Temperature	0° C to +50° C (32° F to 122° F)
Transport/Storage Humidity	0% to 90%, non-condensing
Protection Against Ingress of Fluids	Splash resistant
Chemical Resistance	Resistant to isopropyl alcohol
Input Voltage	
Touch Screen	100 – 240 VAC, 50/60 Hz
CPU	100 – 240 VAC, 50/60 Hz

## Electrical Safety

The operator's manual for each individual component shall be used to determine the Electrical Safety Standards that each product complies with.

When the NxStage System One and OneView are setup as a system by NxStage Medical, Inc. or its agent, the entire System shall meet the requirements of:

IEC 60601-1-1:2000 2nd Edition – Medical Electrical Equipment – Part 1-1: General requirements for safety – Collateral standard; Safety requirements for medical electrical systems.

### **Electromagnetic Compatibility (EMC)**

The operator's manual for each component shall be used to determine the EMC and/or FCC Standards that the product complies with.

### **Operation**

OneView operates only with the NxStage System One. Data is received from the cyclor through the computer serial port. One way communication only (cyclor to PC via IR).

Refer to the Instructions for Use and Specifications packaged with the specific processor and touch-screen provided with the OneView.



NxStage Medical, Inc.  
439 South Union Street  
5th Floor  
Lawrence, MA 01843  
Tel 978-687-4700  
Fax 978-687-4800

**For NxStage Customer Service:**  
**Tel: 866-697-8243**  
**Fax: 978-687-4709**  
**E-mail: [customerservice@nxstage.com](mailto:customerservice@nxstage.com)**

Portions by ComponentOne. ©ComponentOne LLC 1991-2001. All Rights Reserved.

Warning: this computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.

NxStage® is a registered trademark of NxStage Medical, Inc. All other trademarks are the property of their respective owners.  
©2003 NxStage Medical, Inc.

NC0329, Rev. D  
07/22/03